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MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005
PHONE (202) 383-2866
FAX (202) 789-1748
http://www.monsanto.com

March 20, 2006

Document Processing Desk Registration Division – H7505C U.S. Environmental Protection Agency 1801 South Bell Street Crystal Mall #2, Room 266A Arlington, Virginia 22202-4501

Attention:

Mr. James A. Tompkins

Product Manager 25

Subject:

MON 78365 Herbicide QuikPRO Herbicide EPA Reg. No. 524-535

**Certification of Child Resistant Packaging** 

#### Dear Mr. Tompkins:

Monsanto herein requests the Agency approval of child resistant packaging for the 1.5 oz foil pouch for QuikPRO Herbicide. This label is based on the EPA Stamped label dated May 12, 2003.

After a meeting between Monsanto and the Agency January 13, 2005, in a letter dated February 8, 2005, Monsanto agreed to research child resistant packaging options for package skus of QuikPRO herbicide. Pursuant to requirements in 40 CFR Part 157.22, and 157.34, Monsanto submitted certification to child-resistant packaging for the 6.8 lb package of QuikPRO herbicide, MON 78365 and distributor supplemental product, Lesco Prosecutor Swift Acting, 524-535-10404 in a letter dated January 24, 2006. Monsanto selected a Van Blarcom Closure, Saf Cap III-A, ASTM certified type I closure compliant with CFR Title 16, Part 1700 and on the EPA list of approved CRP vendors.

Monsanto contracted with National Child Resistant Testing Inc (NCRT) to perform a Sequential Child Test and a Senior Adult Use Effectiveness Test on a new pouch and material to determine if the package meets the requirements of 16 CFR 1700. The results of this testing are attached.

Pursuant to the results of this testing, I certify that the packaging used for this product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995). The type of package is a sealed 4 3/16 x 5 ¾ inch foil pouch made of 3 mil valeron/7#LDPE/ 0.00035" foil/7# EMAA/1.25 Mil Surlyn Film manufactured by American Packaging.

This amendment is classified as part of the Agency's Fast-Track Program and therefore no fee is due. The following documents are included with this notification:

Application for Pesticide (form 8570-1)
Final Report dated February 23, 2006 from NCRT
Existing pouch artwork and revised pouch artwork

If you should have any questions regarding this submission, please call Dr. Russell P. Schneider at (202) 383-2866 or call me at (314) 694-6576.

Sincerely,

Dawn Fee-White Registration Manager

Dawn Just Tito

Cc w/ attachments:

Russ Schneider

Rosalind L. Gross, Technical Review Branch

J. Winski

File

Attachment: Final Report by National Child Resistant Testing, Inc.

Please read instructions on reverse before completing form.	Form Appro	ved. OMB No. 2070-0080		
United States		Registration	OPP Identifier Number	
SEPA Environmental Protection	· ·	X Amendment	202040	
Washington, DC 2046	0	Other	303848	
Application	n for Pesticide - Sect	ion I		
1. Campany/Product Number	2. EPA Product Mans	ger 3. Pr	oposed Clessification	
Monsanto Company / 524-535	Mr. James To	mpkins	None Restricted	
4. Company/Product (Name) MON-78365; QuikPro Herbicide	PM# 25			
5. Name and Address of Applicent (Include ZIP Code)	6. Expedited Rev	iew. In accordance with	FIFRA Section 3(c)(3)	
Monsanto Company 1300 I (Eye) Street, N.W., Suite 450 Ea		s similar or identical in co	mposition and labeling	
Washington, DC 20005	EPA Reg. No	·····		
Check if this is a now address	Product Name _			
	Section - II			
Amendment - Explain bolow.		l labala in response to		
Resubmission in response to Agency letter deted	Agency lett "Me Too" A			
Notification - Explain below.	Other - Expl			
Explanation: Use additional page(s) if necessary. (For section	LAJ	**************************************	80000480000000000000000000000000000000	
Certification of CRP.				
Monsanto believes this is a fast-track	notification with n	o associated PRIA	fee. Please email	
any fee requirement response to Regulat	ory.Affairs@Monsant	o.com.		
I certify that the packaging that will 40 CRF 157.32	be used for this pr	oduct meets the st	tandard	
	Section - III			
1. Material This Product Will Be Packaged In:				
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging	2. Type of Contains	r	
X Yes X Yes	Yes	Metal Plantic		
No No	IX No	Gless		
* Certification must If "Yes" No. per Unit Packaging wgt. container	If "Yes" No. per Package wgt contains	Paper Y Other (	Spacify) foil pouch	
be submitted 1.5 oz. 5	, i			
3. Location of Net Contents Information 4. Size(s) Ret	ail Container	5. Location of Label Directi On Label	ons	
Lebel X Conteiner 1.5	OZ.	On Labaling accor	***************************************	
6. Manner in Which Lebel is Affixed to Product Lithog Paper Stenoi	reph X Otho glued ed	r <u>printed on foil</u>		
	Section - IV			
1. Contact Point	n of individual to be contacted,	if necessary, to process thi	is application.)	
Name	Title		ne No. (Include Area Code)	
Dr. Russell P. Schneider	Director, Regulato	ry Affairs (202)	383-2866	
Certifica			6. Date Application	
I certify that the statements I have made on this form and I ecknowledge that any knowingly felse or misleading stat	e, accurate and complete. To or imprisonment or	Received (Stamped)		
both under applicable law.	3. Title			
2. Signature	Registration	Manager	50.	
4. Typed Nemo	6. Date			
,,,	March 20, 2006			

FPA Form RE70-1 (Ban B-94) Pravious editions are obsolete



Read the enclosed label booklet before using this product. Lea todo el folleto adjunto antes de usar este producto. Use only according to label histoscitons, Read the "EIMIT OF WARRANTY AND LIABILITY", which appears in the label brooklet, before buying or using. If terms are not ecceptable, return at once unappried, THIS IS ANEND-USE PRODUCT MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION OR REPACKAGING.

Keep out of reach of children.

# CÁUTION! Read precautions in enclosed booklet.

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\*Equivalent to 66.6% of the acid, glyphosate 1.0 pound of QuikPRO\* herbicide contains 0.73 paund of the ammonium salt of glyphosate and 0.03 pound of the dibromide salt of diquat.

# 

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

QuikPRO and Powered by Rounding Technology are reademarks of Monsanto Technology LLC.
Product of Brazil; Formulated in the U.S. with U.S. Ingradients
© 2004 MONSANTO COMPANY, ST. LOUIS, MISSOURI 63167

EPA Est. 065387-AR-001 EPA Reg. No. 524-535 9860581-156PW



Read the enclosed label booklet before using this product. Lea todo et folieto adjunto antes de usar este producto. Use only according to label instructions. Read the "LIMIT OF WARRANTY AND LIABILITY" statement, which appears in the label booklet, before buying or using. If terms are not acceptable, return at once unopened. THIS IS AN END-USE PRODUCT. MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION OR REPACKAGING.

Keep out of reach of children.

# CAUTION! Read precautions in enclosed booklet.

ACTIVE INGREDIENTS: 

\*Equivalent to 66.6% of the acid, glyphosate.

1.0 pound of QuikPRO\* herbicide contains 0.73 pound of the ammonium salt of glyphosate and 0.03 pound of the dibromide salt of diquat.

#### **NET 1.5 OZ**

THIS MULTIPACK UNIT HOT LABELED FOR INDIVIDUAL SALE

See label booklet for Complete Directions for Use.

in case of an emergency involving this product, Call Collect, day or night, (314) 694-4000. 

# National Child Resistant Testing, Inc.



QuickPRO 1.5oz. Pouch

Final Report

Prepared For Monsanto Company

February 23, 2006

National Child Resistant Testing, Inc. 610 West Cuming Street, Lincoln, Nebraska 68521 (402)438-0216

#### 1 GENERAL INFORMATION

Client:

Monsanto Company

800 North Lindbergh Blvd.

St. Louis, MO 63167

Purchase Order:

4508903354

Service Requested:

The client has requested a Sequential Child Test and a Senior

Adult Use Effectiveness Test be conducted on a pouch to

determine if the package meets the requirements of 16 CFR 1700

(Revised July 21, 1995).

Test Performed:

Senior Adult Use Effectiveness Test and Sequential Child Test

per 16 CFR 1700

Test Start Date:

2/07/2006

Test End Date:

2/22/2006

NCRT Job #:

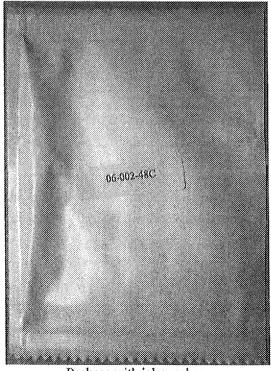
06-002

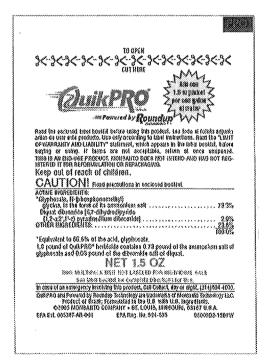
Summary of Results:

The testing data indicate the package meets the standard for

child-resistant packaging as it is defined in the Code of Federal

Regulations 16 CFR 1700.





Package with job number

Print with opening instructions

National Child Resistant Testing, Inc.

#### QuickPRO 1 5oz. Pouch Final Report for Monsanto Company

#### 2 TEST PROTOCOL

#### 2.1 PACKAGE DESCRIPTION

- 211 Pouch
  - Material: 3 Mil Valeron/7# LDPE/ 0.00035" Foil/7# EMAA/1.25 Mil Surlyn Film
  - Manufacturer. American Packaging
  - Spec #. AP1088
  - Finished Pouch Dimensions (approximate): 4 3/16 x 5 3/4 inches
- 2.1 2 Opening Instructions Scissors symbol at top of pouch with the following text. "TO OPEN, CUT HERE"

#### 2.2 SAMPLE PREPARATION

- 2.2.1 The adult test samples were prepared in pairs and labeled with an identification number consisting of the NCRT job number (06-002) and a sequential sample number from 1 to 100. The pairs were differentiated with an "A" and "B" designation (e.g. 06-002-10A & 06-002-10B)
- 2.2 2 The child test samples were labeled with an identification number consisting of the NCRT job number (06-002), a sequential sample number from 1 to 50 and a "C" designation (e.g. 06-002-10C).
- 2 2.3 Twenty-five pouches were labeled with "Demo" to be used for demonstration during the child test

#### 2.3 PROCDURES

- 2.3 1 The following procedures from the Code of Federal Regulations were used to conduct the test.
  - Semor Adult Test 16 CFR 1700.20 (a)(3)
  - Sequential Child Test- 16 CFR 1700 20 (a)(2)
- All instructions given to the children and adult participants are detailed in the above regulatory citations.
- 2 3 3 At the beginning of the test, the adult participants were given a paper copy of the package artwork which included the opening instructions. The artwork was provided by Monsanto
- 2.3.4 The children were given one pouch at the beginning of the test.

#### 2.4 TEST PARTICIPANTS

- 2 4 1 100 adults (50-70 years), broken into three age groups (25%, 50-54 years; 25%, 55-59 years; 50%, 60-70 years). Gender breakdown of 70% female and 30% male in each age group
- 2.4.2 50 children (42-51 months), broken into three age groups (30%, 42-44 months, 40%, 45-48 months; 30%, 49-51 months). Gender breakdown of 50% female and 50% male with a 10% difference allowed in each age category.

National Child Resistant Testing, Inc.

#### QuickPRO 1 5oz Pouch Final Report for Monsanto Company

#### 2.5 FAILURE DEFINITIONS

- 2 5.1 Senior Adults. Any adult who was unable to open the package during the first fiveminute test period, but was able to pass the screening test was counted as a failure. Or, any adult who was unable to open the package during the second one-minute test period was counted as a failure.
- 2 5.2 Children. Any child who was able to gain partial access to the inside of the pouch

#### 3 RESULTS

#### 3.1 SENIOR ADULT TEST RESULTS

3.1.1 One hundred adults (100%) successfully opened the packages in both the 5-minute and the 1-minute test periods. The results are summarized in Table 1. The adult test sites are summarized in Table 2. The adult testers are summarized in Table 3.

#### 3.1.2 Statistics

- Mean opening time of the 5-minute period was 15 seconds, Std. Dev. of 17
- Mean opening time of the 1-minute period was 6 seconds, Std. Dev of 7

Table 1 Adult panel, Total Packages Opened

	Pane	elists		Successful Openings			
Age				Opened in Test I		Opened m Test I	
(Years)	Total	Males	Females	Male	Female	Male	Female
50 –54	25	8	17	8	17	8	17
55 -59	25	7	18	7	18	7	18
60 –70	50	15	35	15	35	15	35
Totals	100	30	70	30	70	30	70

Table 2
Summary of Adult Test Sites

Test Site	Number of Adults Tested	% of Total Panel
2	24	24
3	1	1
4	11	11
5	2	2
9	24	24
10	1	1
13	24	24
16	13	13
Total	100 Adults	100%

National Child Resistant Testing, Inc

Page 4 of 9

#### QuickPRO 1.5oz. Pouch Final Report for Monsanto Company

Table 3 Summary of Adult Testers

Tester	Number of Adults Tested	% of Total Panel		
CSN	12	12		
MN	29	29		
EE	35	35		
PB	24	24		
Total	100 Adults	100%		

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#### 3.2 CHILD TEST RESULTS

- 3 2 1 Of the 50 children tested, one child successfully gained access to the inside of the pouch during the 10-minute test. The one opening occurred in the first five-minute period prior to the demonstration
- 3 2.2 The results are summarized in Table 4. The individual failures are described in Table 5. The child test sites are summarized in Table 6. The child testers are summarized in Table 7
- 3 2.3 Statistics The mean opening time and standard deviation do not apply because only one of the children opened the package (opened in first 5-minute period)

Table 4 Child Panel, Results

	Pan	elists			Succ	essful Ent	ries	
				Before Do	emonstration	After De	monstration	Total
Age (Months)	Total	Males	Females	Males	Female	Males	Female	Entries
42 - 44	15	8	7	0	0	0	0	0
45-48	20	10	10	0	0	0	0	0
49 - 51	15	8	7	1	0	0	0	1
Totals	50	25	25	1	0	0	0	1

Table 5
Child Panel, Detail of Individual Failures

		-		Cities a many and other than and the	
	Sample	Candar	Age	Time of Entry	Entry Description
-	#	Gender	(mo)	(total elapsed seconds)	Entry Description
	44	M	50	181	Peeled at corner and tore open

National Child Resistant Testing, Inc

#### QuickPRO 1.5oz Pouch Final Report for Monsanto Company

Table 6
Child Panel. Test Site Summary

Test Site	Number of Children Tested	% of Total Panel
2	10	20
17	10	20
13	10	20
58	3	6
40	3	6
72	3	6
73	2 1	4
21	1	2
27	4	8
29	4	8
Total	50 Children	100%

Table 7

Child Panel, Tester Summary

Tester	Number of Children Tested	% of Total Panel
CSN	15	30
EE	15	30
MN	5	10
CM	10	20
SS	5	10
Total	50 Children	100%

### 4 CONCLUSION

The testing data indicate the package meets the standard for child-resistant packaging as it is defined in the Code of Federal Regulations 16 CFR 1700. The adult use effectiveness was found to be 100%.

Submitted By	Chris Nacrad	Date <u>2-23-66</u>
•	Chris Novosad	

National Child Resistant Testing, Inc.

Page 6 of 9

# 5 DATA TABLES

# **Senior Adult Test Data**

				Demoi 1	Accent E	
_			5-min	1-min		
Sample	G 1		Open Time	Open Time	Result	Comments
#	Gender	Age	(sec)	(sec)	Pass/Fail	Comments
1	M	55	3	2	P	
2	F	58	3	2	P	**
3	F	51	11	11	P	
4	F	59	6	11	P	
5	F	60	2	2	P	
6	M	69	6	2	P	
7	F	56	3	3	P	
8	M	54	1	1	P	
9	F	57	2	1	P	
10	F	58	2.	2	P	
11	F	50	3	1	P	
12	F	65	1	2	P	
13	F	51	2	1	P	
14	M	54	2	2	P	
15	M	63	2	2	P	
16	F	52	1	2	P	
17	F	59	4	1	P	
18	M	58	3	3	P	
19	F	57	2	3	P	
20	M	63	2	2	P	
21	F	62	1	2	P	
22	F	54	13	1	P	
23	F	68	8	3	P	
24	F	54	1	1	<u>P</u>	
25	F	60	22	2	P	
26	M	51	23	9	P	
27	F	59	17	3	<u> P</u>	
28	F	64	16	4	P	
29	F	63	10	4	P	
30	F	68	6	13	P	
31	F	61	15	6	P	
32	F	54	7	5	P	
33	F	60	18	4	P	
34	F	60	10	4	P	
35	M	53	6	13	P	
36	M	61	3	2	P	
37	F	52	5	4	P	
38	F	69	9	7	P	
39	M	66	25	3	P	
40	F	54	26	3	P	
41	M	57	31	9	P	***************************************
42	M	58	3	3	P	
43	F	50	8	2	P	
44	M	62	22	2	P	
45	F	66	10	32		
46	M	59	5	5	P P	
47						
	F	50	8	2	P	
48	F	56	8	6	P	
49	M	62	11	5	P	

National Child Resistant Testing, Inc

QuickPRO 1.5oz Pouch Final Report for Monsanto Company

Sample	C3		5-min Open Time	1-min Open Time	Result	Comments
# 50	Gender F	Age 56	(sec) 15	(sec) 3	Pass/Fail P	Conditents
		58				
51	M		10	3	P	
52	M	60	17	5	<u>P</u>	
53	F	57	35	11	P	
54	F	60	5	9	P	
55	M	51	6	2	P	
56	F	66	26	4	P	
57	F	54	5	6	P	
58	F	69	25	66	P	
59	F	66	13	3	P	
60	F	58	13	4	P	
61	F	69	17	6	P	
62	M	53	8	2	P	
63	F	57	3	3	P	
64	F	59	21	9	P	
65	F	54	6	4	P	
66	F	60	17	4	P	
67	F	66	9	4	P	
68	M	54	6	4	P	
69	M	60	35	12	P	
70	F	57	6	4	P	
71	F	58	3	6	P	
72	M	68	28	8	P	
73	F	60	3	6	P	
74	F	57	46	6	P	
75	F	64	21	44	P	
76	M	57	6	3	P	
77	F	61	109	9	P	
78	F	61	7	2	P	
79	F	68	10	10	P	
80	F	69	15	4	P	
81	M	70	38	13	P	
82	F	61	9	4	P	
83	F	61	35	13	P	
84	F	51	6	6	P	
85	F	52	9	3	P	
86	F	60	5			
87	M	60	5	5	P	
88	F	51	10			
89				5	P	
90	F	51	13 .	10	P	
	F	69	24	3	P	
91	M	50	81	5	P	
92	F	59	7	3	P	
93	M	67	12	23	P	
94	F	66	50	38	P	
95	M	68	13	12	P	
96	F	64	57	10	P	
97	F	63	19	4	P	
98	M	64	17	3	P	
99	F	66	51	21	P	
100	F	67	49	7	P	

Notional Child Resistant Testing, Inc

Page 8 of 9

### QuickPRO 1 Soz Pouch Final Report for Monsanto Company

### **Child Test Data**

Ciniu i est Data										
Sample		Age	Time of Entry	N. 6. 43 3 D. T. S						
#	Gender	(mo)	(elapsed seconds)	Method of Entry						
1	M	49								
2	M	51								
3	F	47								
44	F	48								
5	M	48								
6	M	47		<b>,</b> A						
7	M	48								
8	M	47								
9	F	45								
10	M	46								
11	M	47								
12	F	51								
13	F	45								
14	M	46								
15	F	43								
16	F	44								
17	M	43								
18	F	44								
19	F	44								
20	M	44	***************************************							
21	F	44								
22	M	49								
23	M	43								
24	M	42								
25	M	47								
26	F	46								
27	F	47								
28	F	44								
29	M	43								
30	F	43								
31	M	45								
32	F	50								
33	F	47								
34	F	48								
35	M	50								
36	M	50								
<u>30</u>	F									
		46								
38 39	M	42								
	M	51								
40	M	48								
41	F	49								
42	M	44								
43	M	42								
44	M	50	181	Peeled at corner and tore open						
45	F	48								
46	F	49								
47	F	51								
48	F	51								
49	M	50								
50	F	50								

National Child Resistant Testing, Inc.

Page 9 of 9

#### FEE-WHITE, DAWN M [AG/1000]

From: Sent:

Gross.Rosalind@epamail.epa.gov Wednesday, April 19, 2006 4:03 PM FEE-WHITE, DAWN M [AG/1000] Walters. Vickie@epamail.epa.gov

To: Cc:

Re. Monsanto QuikPRO CRP Subject:



**Customer Test** Agreement - Mons.. Dawn

It was good to talk with you this morning. As noted here are my comments regarding the child test . Please note there is one comment to the customer test agreement. It is The 50% male 50% female distribution of the child panel is for each age group. If you have any questions please feel free to call me. I will be in the office tomorrow.

Notes on EPA Reg. No. 524-535 CRP Testing

The children should be given 5 pouches at the beginning of the test. A placebo of rice is acceptable.

The definition of a child failure should be access to any amount of one pouch The definition of a pouch failure should be access to any amount of one pouch by any means such as puncture (even by one tooth), tear, open, etc. Note the placebo does not have to come out of the pouch the potential for placebo access such as through a tooth puncture is sufficient for a pouch failure. This approach is being adopted based on a worst case scenario calculation of a toxic or harmful amount of the product to an 11.4kg child, which is 118.2mg and a pouch contains 42,500 mg of the product.

The 50% male 50% female distribution of the child panel is for each age group. note this in the customer test agreement, which you sent me 4/18/06.

The final child report should include: a statement that the pouch was tested with placebo resembling the product; a statement that the number of pouches each child received at the beginning of the test was 5; a photograph of the pouch tested; a description of the material composition of the pouch.

The child study should be submitted in hard copy as well as electronic copy per PR 97-9. The test date and birth date fields should be numeric. The senior adult study should be resubmitted in hard copy with the electronic copy per PR 97-9. The test date and birth date fields should be numeric. The CD should be closed so that nothing else can be written to it. Copies of the CD should be retained in case something happens to the Agency copy and it needs to be resubmitted or certain fields need to be corrected.

Save all child test samples until the Agency accepts the data. Rosalind Gross Registration Division CM-2, Room 262 1801 South Bell St. Arlington, VA 22202 telephone 703-308-7368 fax 703-308-9382 email gross.rosalind@epa.gov

> "FEE-WHITE, DAWN M [AG/1000]" <dawn.m.fee-whi te@monsanto.com

Rosalind Gross/DC/USEPA/US@EPA

CC

TO

Subject

Monsanto QuikPRO CRP

04/18/2006 04 · 02 PM

Rosalind, thank you for the time last week on the phone. We had discussed possible review of the protocol and the number of pouches that may be necessary to fulfill the testing requirements. The National Child Resistant Testing that will performing our Child Resistant Test, has provided the attached outline of the re-test plan. Will this be sufficient? I've asked that they specify uncooked rice (rather than just rice) as the placebo. According to my manufacturing contact, this substance most closely resembles the QuikPRO product. As for the specific details of the testing protocol, they would follow the requirements of 1700.20. Please advise if the attached will fulfill our re-testing requirement or if we need to provide more than 5 pouches per child. Remember this is only sold in a box of five (5) 1.5 oz pouches. I seriously don't expect marketing to ever want to sell in higher units. Thanks for your direction.

Dawn Fee-White Monsanto 314-694-6576

<<Customer Test Agreement - Monsanto 06-011.doc>>

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January 24 2006

Document Processing Desk (NOTIF)
Registration Division – H7505C
U.S. Environmental Protection Agency
1801 South Bell Street
Crystal Mall #2, Room 266A
Arlington, Virginia 22202-4501

Attention

Mr James A Tompkins Product Manager 25

Subject

MON 78365 Herbicide QuikPRO Herbicide; EPA Reg. No. 524-535

Notification of Final Printed labeling and voluntary Certification of Child Resistant

Packaging

Dear Mr Tompkins

Monsanto herein notifies the Agency of a revised final printed label for QuikPRO Herbicide, print plate 90005E4-12/53. This label is based on the EPA Stamped label dated May 12, 2003. Revisions to this approved version were previously notified to the Agency November 9, 2004. This most recent printing simply resizes the booklet to fit the new child resistant packaging. No precautionary or use instruction changes have been made.

In addition, after a meeting between Monsanto and the Agency January 13, 2005, in a letter dated February 8, 2005, Monsanto agreed to research child resistant packaging options for package skus of QuikPRO herbicide. Pursuant to requirements in 40 CFR Part 157 22, and 157 34, Monsanto is submitting certification to child-resistant packaging for the 6 8 lb package of QuikPRO herbicide, MON 78365 and distributor supplemental product, Lesco Prosecutor Swift Acting, 524-535-10404 Monsanto has selected a Van Blarcom Closure, Saf Cap III-A, ASTM certified type I closure compliant with CFR Title 16, Part 1700 and on the EPA list of approved CRP vendors

This notification is classified as part of the Agency's Fast-Track Program and therefore no fee is due. The following documents are included with this notification.

Application for Pesticide (form 8570-1)
Three copies of final printed label

If you should have any questions regarding this submission, please call Dr. Russell P. Schneider at (202) 383-2866 or call me at (314) 694-6576

Sincerely,

Dawn Fee-White Registration Manager

Daven Jew Thill

Cc w/ attachments

Russ Schneider

Rosalind L Gross, Technical Review Branch

Attachment Component Specification

United St	United States			ation	OPP Identifier Number 303827					
<b>EPA</b> Environmental Pro		Agency	Amendi	nent	303027					
Washington, D	JC 20460		Other							
Application for Pesticide – Section I										
1 Company/Product Number 524-535		2 EPA Product Manager James A Tompkins 3 Proposed Classification								
4 Company/Product (Name)					None					
MON 78365, QUIKPRO HERBICIDE / Monsanto C	Company	25 Restrict								
5 Name and Address of Applicant (Include ZIP Code) Monsanto Company 1300 I Street, NW, Suite 450 East		6 Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to EPA Reg No								
Washington, DC 20005										
Check if this is a new address	04	Product Name								
Section – II										
Amendment – Explain below		Final printed labels in response to Agency letter dated								
Resubmission in response to Agency letter dated		"Me Too" Application								
Notification – Explain below		Other – Explain below								
Explanation: Use additional page(s) if necessary (For section I and Section II)  Monsanto believes this is a fast-track notification with no associated PRIA fee. Please e-mail any fee requirement response to Regulatory.Affairs@Monsanto.com. Notification of final printed label.										
I certify that the packaging that will be used for this p	roduct mee	ets the standards of	40 CFR 157.32	•						
Section – III										
Material This Product Will Be Packaged In										
Child-Resistant Packaging  Yes*  No  No  Unit Packaging  No  No		Water Soluble Packaging  Yes  No  Plastic  Glass								
* Certification must be submitted If "Yes" No per Unit Packaging wgt Container 6 8 lb 2	Package wgt Container			aper ther (Specify)						
1	Retail Contair	tail Container 5 Location of Label Directions			18					
Label Container 6 8 lb		On Label On Labeling accompanying product								
6 Manner in Which Label is Affixed to Product Lithograph Other										
in mold labeling with labeling under Paper glued Paper glued										
measuring cap . Stenciled  Section – IV										
1 Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)										
Name Russell P Schneider Ph D	Title C				e No (Include Area Code) (202) 383-2866					
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law  6 Date Application Received (Stamped)										
2 Signature  Warm Luce hile		3 Title Registration Manager								
4 Typed Name Dawn M Fee-White	5 Date	Date 26 January 2006								



1300 I (Eye) STREET, NW SUITE 450 EAST WASHINGTON, D C 20005 PHONE (202) 383-2866 FAX (202) 789-1748 http://www.monsanto.com

February 8, 2005

Document Processing Center
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention.

Mr. James A. Tompkins

Team Leader (25)

Subject:

MON 78365 Herbicide QuikPRO Herbicide EPA Reg. No. 524-535

**Determination on Applicability of Child Resistant Packaging** 

Requirements

Dear Mr. Tompkins:

On January 13, 2005, Dr. Russell Schneider, Mr. Tom Carratto, Monsanto Associate General Counsel, and I, met with Dr. Rosalind Gross and Ms. Vickie Walters to review Monsanto's request for an exemption from child-resistant packaging requirements (Letter dated November 8, 2004) pursuant to 40 CFR Part 157.24(b), for formulations currently approved under EPA registration number 524-535.

We would like to thank Dr. Gross and Ms. Walters for their time and we greatly appreciate their efforts in explaining the process for such exemption requests and Dr. Gross' suggested alternatives for how Monsanto might proceed on this matter.

During our meeting, it was suggested that Monsanto seek a determination from the Registration Division as to whether or not the CRP requirements for acute inhalation toxicity are applicable to MON 78365 herbicide (alternate brand name: QuikPRO herbicide), considering that 1) the acute inhalation toxicity study could not be conducted on the dry product as commercially packaged and 2) there is essentially no concern for inhalation exposure as only a negligible percentage (0.002%) of particles from this dry product are in the respirable range of less than 10 microns.

As stated in our exemption request letter dated November 8, 2004, due to its physical characteristics there is no practical means by which to determine the acute inhalation LC50 value of the undiluted granular product. In addition, given that there are essentially no particles in the respirable range, young children who may come in contact with the packaged product would experience negligible exposure via inhalation. For these reasons, there is no risk of serious injury or illness from accidental exposure to this product that would be reduced by the use of child-resistant packaging. Thus, Monsanto believes that the formulation currently approved under this registration should not be subject to child-resistant packaging requirements on the basis of the acute inhalation  $LC_{50}$  as determined in the submitted study (MRID 45434304). According to Dr. Gross, an evaluation of this information and a subsequent determination would appropriately be made by the technical reviewer in the Technical Review Branch who originally reviewed the acute toxicity studies supporting this registration approval.

Because of the ambiguity that exists with regard to the applicability of the CRP standards to this product, Monsanto is in the process of researching packaging options for this product. While the above request is being considered by the Agency, Monsanto intends to begin immediately with our next scheduled production utilizing child-resistant packaging for both package SKUs of QuikPRO herbicide.

If you have any questions regarding this request feel free to contact me through Dr. Russell P. Schneider at 202-383-2866 or directly at 314-694-8890.

Sincerely,

Annette M. Kırk Registration Manager

Amet M York

R P. Schneider J B Winski